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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,078	07/16/2003	Travis G. Young	92-02	1840
23713 7590 02/01/2007 GREENLEE WINNER AND SULLIVAN P C 4875 PEARL EAST CIRCLE SUITE 200 BOULDER, CO 80301			EXAMINER RUSSEL, JEFFREY E	
			ART UNIT	PAPER NUMBER
			1654	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		02/01/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/622,078

Applicant(s)

YOUNG ET AL.

Examiner

Jeffrey E. Russel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-50,57-62 and 67-75 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-50,57-62 and 67-75 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>20060817</u> . | 6) <input type="checkbox"/> Other: _____ |

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1. Applicant's election with traverse of the invention of Group II, and the species $-(CH_2)_m-$ and $-(CR_2)_m-$, in the reply filed on August 17, 2006 is acknowledged. The traversal is on the ground(s) that the generic claims are allowable, and as such the examination should be extended to the nonelected species. This is not found persuasive because the generic claims are not found to be allowable, for the reasons set forth below.

The requirement is still deemed proper and is therefore made FINAL.

It should be noted that the election requirement set forth in the Office action mailed April 24, 2006 does not require election between the species $-(CH_2)_m-$ and $-(CR_2)_m-$, and does not require election among values of m.

2. The Sequence Listing filed November 12, 2004 is approved.

The replacement pages contained in the amendment filed August 17, 2006 have not been entered or considered. There is no provision in the rules for the use of replacement pages.

3. The disclosure is objected to because of the following informalities: At page 39, lines 11, 21, 23, and 29, and at page 43, line 3, SEQ ID NOS must be inserted after the amino acid sequences. See 37 CFR 1.821(d). Appropriate correction is required.

4. Claims 50 and 57-62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The preamble to claim 50 recites that a peptide "or amino acid" is to be synthesized. However, the sole method step recited in the claim requires that a peptide be synthesized. It is not clear what the relationship is between the preamble's statement that an amino acid is to be synthesized, and the method step which states that a peptide is to be synthesized, because synthesis of a peptide is usually not an intermediate step in the synthesis of

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an amino acid. Further, there is no antecedent basis in the claims for the phrase "the... protein" in claim 57. Note that claim 50 does not mention the synthesis of proteins.

5. Claims 18-50, 57-62, and 67-75 are objected to because of the following informalities:

At claim 18, line 6, "an" should be deleted. At claim 21, line 2, and claim 33, line 2, "Fmoc" is repeated, and the semicolon after the second occurrence of "Fmoc" should be changed to a comma. Appropriate correction is required.

6. Applicant is advised that should claims 34, 69, and 73 be found allowable, claims 38, 70, and 74 will be objected to under 37 CFR 1.75 as being substantial duplicates thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim 38 is identical in scope with claim 34. It is believed that claim 38 should instead depend upon claim 37.

Claims 69 and 70 are identical in scope, and claims 73 and 74 are identical in scope. Note that claims 69 and 73 depend upon claims which require R to be H.

7. Instant claims are deemed not to be entitled under 35 U.S.C. 119(e) to the benefit of the filing date of provisional application 60/396,832 because the provisional application, under the test of 35 U.S.C. 112, first paragraph, does not disclose an R' group which is N-hydroxysuccinimido. Accordingly, the Young PhD thesis is available as prior art against these claims under 35 U.S.C. 102(b).

Instant claim 29 is deemed to be entitled under 35 U.S.C. 119(e) to the benefit of the filing date of provisional application 60/396,832 because the provisional application, under the

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test of 35 U.S.C. 112, first paragraph, discloses the claimed invention. Accordingly, the Young PhD thesis is available as prior art against this claim under 35 U.S.C. 102(a).

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

For the purposes of this invention, the level of ordinary skill in the art is deemed to be at least that level of skill demonstrated by the patents in the relevant art. *Joy Technologies Inc. v.*

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Quigg, 14 USPQ2d 1432 (DC DC 1990). One of ordinary skill in the art is held accountable not only for specific teachings of references, but also for inferences which those skilled in the art may reasonably be expected to draw. In re Hoeschele, 160 USPQ 809, 811 (CCPA 1969). In addition, one of ordinary skill in the art is motivated by economics to depart from the prior art to reduce costs consistent with desired product properties. In re Clinton, 188 USPQ 365, 367 (CCPA 1976); In re Thompson, 192 USPQ 275, 277 (CCPA 1976).

9. Claims 18-28, 67-70, and 75 are rejected under 35 U.S.C. 102(b) as being anticipated by the Young PhD thesis. The Young PhD thesis teaches tyrosine protected at its N-terminus with Fmoc or Boc and at its hydroxyl group with azidomethyl. The protected tyrosine residue is used in the solid phase synthesis of peptides, where the azidomethyl protecting group is cleaved and the unprotected hydroxyl group is sulfated prior to cleavage of the peptide from the solid phase resin. The resin used for solid phase synthesis is 2-chlorotrityl resin. The Young PhD thesis also teaches that the same azidomethyl protecting group can be used to protect the hydroxyl functions of serine or threonine residues during solid phase peptide synthesis, and that after removal of the azidomethyl protecting group, the hydroxyl functions can be subject to phosphorylation or glycosylation. See, e.g., page 55, Figures 2.22 and 2.23; page 58, Figure 2.27; page 74, line 1 - page 75, line 5; and page 126, line 15. Other azido-based protecting groups are taught at page 76, Figure 3.02.

10. Claims 30-50, 57-62, and 71-74 are rejected under 35 U.S.C. 103(a) as being obvious over the Young PhD thesis. Application of the Young PhD thesis is the same as in the above rejection of claims 18-28, 67-70, and 75. The Young PhD thesis does not teach packaging the reagents used for its reactions in a kit form optionally including instructions for use. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to package the reagents used by the Young PhD thesis in a kit form optionally including instructions for use because kit forms with instructions for use are well-known means for

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packaging chemical reagents, and have the benefit of easing the storage, transportation, measurement, and use of the reagents.

11. Claim 29 is rejected under 35 U.S.C. 103(a) as being obvious over the Young PhD thesis as applied against claims 18-28, 67-70, and 75 above, and further in view of Heavner (U.S. Patent No. 4,369,137) or Lam et al (U.S. Patent No. 5,858,670). The Young PhD thesis does not teach a tyrosine residue protected at its sidechain with an azidomethyl group and activated at its C-terminus with chloride. Heavner teaches that it is well-known in the art to activate the carboxy group of protected amino acids as an acid chloride prior to peptide synthesis. See, e.g., column 5, lines 18-22, and column 8, lines 25-33. Lam et al teach that in order to attach a blocked amino acid to a peptide chain during solid phase peptide synthesis, the carboxyl group must be activated, and that the acid chloride method of activation is known in the art. See, e.g., column 7, line 44 - column 8, line 4. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to activate the carboxyl group of the protected tyrosine residue of the Young PhD thesis via the acid chloride method as taught by Heavner and by Lam et al, because it is necessary to activate the carboxyl group so that it can be used in peptide synthesis, and because activation as an acid chloride is a well-known method of activation of blocked amino acids which are to be used in peptide synthesis.

12. Claims 18, 19, 21, 22, 67, 68, and 75 are rejected under 35 U.S.C. 102(a) and (e) as being anticipated by Brooks et al (U.S. Patent No. 6,500,924). Brooks et al teach compound 3 (see Figures 38 and 39) which meets the requirements of Applicants' formula in which PR is Boc, R is H, n=1, A is phenyl, M is $-(CH_2)_4-$, and R' is O-Benzyl. The compound is used to synthesize $\alpha_v\beta_3$ antagonists (see, e.g., column 8, lines 40-42), which synthesis method includes a step of

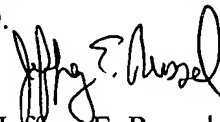
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deprotecting the N-terminus of compound 3 with TFA (see Figure 38). The tyrosine residue has the L-configuration (see column 58, line 66).

13. Claims 30, 31, 33, 34, 38, 45, and 49 are rejected under 35 U.S.C. 103(a) as being obvious over Brooks et al (U.S. Patent No. 6,500,924). Application of Brooks et al is the same as in the above rejection of claims 18, 19, 21, 22, 67, 68, and 75. Brooks et al do not teach packaging the reagents used for its reactions in a kit form optionally including instructions for use. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to package the reagents used by Brooks et al, including compound 3, in a kit form optionally including instructions for use because kit forms with instructions for use are well-known means for packaging chemical reagents, and have the benefit of easing the storage, transportation, measurement, and use of the reagents. With respect to instant claim 49, the content of the instructions for use do not impart patentability to the claimed kit because there is no functional relationship between the subject matter of the instructions and the kit. See MPEP 2112.01(III).

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:00 A.M. to 5:30 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Cecilia Tsang can be reached at (571) 272-0562. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.


Jeffrey E. Russel
Primary Patent Examiner
Art Unit 1654

JRussel
January 23, 2007